T1A-139US

Appln. No.: 10/577840

Amendment Dated June 4, 2009

Reply to Office Action of March 11, 2009

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

## 1, - 12, (Cancelled)

- (Withdrawn) A method to obtain an immunotherapeutic agent that contains cell wall fragments from a virulent Mycobacterium tuberculosis-complex (MTB-C) strain of cells comprising the sequential steps of
  - a) culturing the cells for a period of at least three weeks and
  - b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds.
- 14. (Withdrawn) The method according to claim 13 wherein the cell culturing period ranges from 3 to 4 weeks.
- 15. (Withdrawn) The method according to claim 13 wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
- 16. (Withdrawn) The method according to claim 15 wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
- 17. (Withdrawn) The method according to claim 16 wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
- 18. (Withdrawn) The method according to claim 13 wherein the cells are homogenized in a buffered medium having a neutral pH.
- (Withdrawn) The method according to claim 18 wherein the medium is buffered with PBS buffer.
- 20. (Previously Presented) An immunotherapeutic agent obtained by the method according to claim 13.
- 21. (Withdrawn) The method according to claim 13 further comprising the steps of

Amendment Dated June 4, 2009

- c) centrifuging the homogenized cell mixture to separate the cell wall fragments from the non-fragmented cells and the solubilized cell compounds,
- d) washing the cell wall fragments and further treating the cell wall fragments to inactivate any remaining virulent cells, and
- e) lyophilizing the resulting immunotherapeutic agent.
- 22. (Withdrawn) The method according to claim 21 wherein the cell culturing period ranges from 3 to 4 weeks.
- 23. (Withdrawn) The method according to claim 21 wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
- 24. (Withdrawn) The method according to claim 23 wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
- 25. (Withdrawn) The method according to claim 24 wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
- 26. (Withdrawn) The method according to claim 21 wherein the cells are homogenized in a buffered medium having a neutral pH.
- 27. (Withdrawn) The method according to claim 26 wherein the medium is buffered with PBS buffer.
- 28. (Previously Presented) An immunotherapeutic agent obtained by the method according to claim 21.
- 29. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 13.
- 30. (Previously Presented) The pharmaceutical composition according to claim 29 in form of liposomes.
- 31. (Previously Presented) The pharmaceutical composition according to claim 30 wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.

Amendment Dated June 4, 2009

- 32. (Previously Presented) The pharmaceutical composition according to claim 30 wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.
- 33. (Previously Presented) The pharmaceutical composition according to claim 30 wherein the sterols are selected from cholesterol and biliar salts.
- 34. (Previously Presented) The pharmaceutical composition according to claim 30, further comprising vitamin E.
- 35. (Withdrawn) A method for the combined treatment of tuberculosis comprising administering the immunotherapeutic agent of claim 20 in combination with at least one drug suitable for the treatment of tuberculosis.
- 36. (Withdrawn) The method of claim 35 wherein the combined therapy is sequential or simultaneous.
- 37. (Withdrawn) The method of claim 35, wherein the drug is selected from the group consisting of isoniazid, rifamplcin, and combinations thereof.
- 38. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 28.
- 39. (Previously Presented) The pharmaceutical composition according to claim 38 in form of liposomes.
- 40. (Previously Presented) The pharmaceutical composition according to claim 39 wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.
- (Previously Presented) The pharmaceutical composition according to claim 40 wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.
- 42. (Previously Presented) The pharmaceutical composition according to claim 40 wherein the sterols are selected from cholesterol and billar salts.

Amendment Dated June 4, 2009

- 43. (Previously Presented) The pharmaceutical composition according to claim 39, further comprising vitamin E.
- 44. (Withdrawn) A method for the combined treatment of tuberculosis comprising administering the immunotherapeutic agent of claim 28 in combination with at least one drug suitable for the treatment of tuberculosis.
- 45. (Withdrawn) The method of claim 44 wherein the combined therapy is sequential or simultaneous.
- 46. (Withdrawn) The method of claim 44, wherein the drug is selected from the group consisting of isoniazid, rifampicin, and combinations thereof.
- 47. (Previously Presented) An immunotherapeutic agent comprising cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain of cells obtained by a process comprising the steps of:
  - a) culturing the cells for a period of at least three weeks, and
- b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds, wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
- 48. (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the cell culturing period ranges from 3 to 4 weeks.
- (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
- 50. (Previously Presented) The immunotherapeutic agent according to claim 49, wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
- 51. (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the cells are homogenized in a buffered medium having a neutral pH.

Amendment Dated June 4, 2009

- 52. (Previously Presented) The immunotherapeutic agent according to claim 51, wherein the medium is buffered with PBS buffer.
- 53. (Previously Presented) The immunotherapeutic agent according to claim 47, wherein the method further comprising the steps of:
- c) centrifuging the homogenized cell mixture to separate the cell wall fragments from the non-fragmented cells and the solubilized cell compounds,
- d) washing the cell wall fragments and further treating the cell wall fragments to inactivate any remaining virulent cells, and
  - e) Ivophilizing the resulting immunotherapeutic agent.
- 54. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 47.
- 55. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 53.
- 56. (Previously Presented) The pharmaceutical composition according to claim 54, in the form of liposomes.
- 57. (Previously Presented) The pharmaceutical composition according to claim 56, wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.
- 58. (Previously Presented) The pharmaceutical composition according to claim 57, wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.
- 59. (Previously Presented) The pharmaceutical composition according to claim 58, wherein the sterols are selected from cholesterol and biliar salts.
- 60. (Previously Presented) The pharmaceutical composition according to claim 59, further comprising vitamin E.